Application No. 10/517,275
Filed on July 25, 2008
Response to Office Action dated February 27, 2008

Remarks:

Claims 1 to 61 are pending in this application. Claims 22, 47, 53 and 55, have been amended.

The Examiner is thanked for a telephone interview dated May 20, 2008 clarifying prior art rejections of record as applied to claims 47 and 55. The Examiner provided clarification that the IL-2 construct disclosed in the cited Qu et al. reference is being interpreted by the Examiner as being relevant to both T cell and antigen presenting cells pathways, and therefore being relevant to both claims 47 and 55. Examiner's guidance is gratefully acknowledged. However, as indicated in greater detail below Applicants respectfully disagree with the Examiner's interpretation.

In the interview the Examiner also provided guidance that the claim objections to claims 22, 27, 47, 48, 53, 55, 56, 57 and 61 for reciting non-elected subject matter is moot as these recitations pertain to species elections only. Examiner's guidance is gratefully acknowledged and accepted.

In the Office Action claims 1 – 21, 23, 25, 28 – 46, 49 – 52, 54, and 58 – 60 are stated to be withdrawn for being directed to a non-elected invention. The claim listing has been revised accordingly. However, Applicants respectfully disagree with the withdrawal of claims 58 – 60. Claims 58 – 60 recite cell types that are members of the antigen presenting cell genus and are intended to define the "at least one construct" recited in predecessor claim 55, and not to recite the administration of these cells *per se* in the claimed method. Accordingly, claims 58 – 60 should be considered as being directed to the elected invention and continued examination of claims 58 – 60 is respectfully requested.

Information Disclosure Statement

With respect to the foreign patent document AU 2003209308 not having been filed, Examiner is advised that the noted document was listed in the Information Disclosure Statement filed on 10/18/2007 on the basis of its citation in an Office Action in a counterpart Australian case. However, no such patent

document exists. The number AU 2003209308 was assigned on the basis of an expected national entry from PCT Application No. PCT/US2003/001726 (WO 2003/061587; Keshavjee et al). Australian national entry of this PCT application has not occurred. Therefore, the citation of AU 2003209308 appears to have been made in error in the Australian Office Action.

Claim Objections

As indicated above the Examiner has indicated in the telephone interview that the objection to claims 22, 27, 47, 48, 53, 55, 56, 57 and 61 for reciting non-elected subject matter is moot as the subject matter in question pertains to a species election.

Claim Rejections Under 35 USC § 112

Claims 47, 48, 53, 55 – 57 and 61 are rejected under 35 USC § 112, first paragraph, for failing to comply with the written description requirement.

Examiner will kindly note that each of the independent claims currently being examined have been amended to recite "produced within an antigen presenting cell". Accordingly, it is clear that the claimed invention is directed to the targeting of a surface marker, chemokine, cytokine, enzyme or transcriptional factor produced within an antigen presenting cell, and not merely any surface marker, any chemokine or any cytokine or any enzyme or any transcriptional factor such that T cell suppression and treatment of transplant rejection of any organ occurs. The targeted molecules are clearly specified to be those produced within an antigen presenting cell. The identity of such molecules is readily recognized by the skilled person. For example, the skilled person is readily aware of cytokines that are produced within antigen presenting cell types. Furthermore, the skilled person is readily able to prepare nucleic acid constructs or more specifically siRNA constructs which can target cytokines that are produced within antigen presenting cell types. The specification as originally filed provides sufficient direction to the skilled person as to possible target molecules and even provides exemplification with respect to targeting of IL-12 and IFN-γ.

The Examiner cited University of Rochester v. G.D. Searle & Co. in support of this rejection. The Examiner will kindly note that in the cited case not a single compound was provided to exemplify the claimed methods. The present claims are thus distinguished from the cited case in that at least two specific compounds have been exemplified.

For at least these reasons claims 47, 48, 53, 55 – 57 and 61 are submitted to be compliant under 35 USC § 112, first paragraph, and withdrawal of Examiner's rejection is respectfully requested.

In the Office Action claim 57 is rejected under 35 USC§112, second paragraph, for a lack of antecedent basis for the term "said immune disorder", with the assertion being made that predecessor claim 55 recites an "autoimmune disorder". The Examiner will kindly note that Applicant's copy of the Amendment dated November 20, 2007, as well as the corresponding copy provided on the PAIR database have both been reviewed and claim 55 has been found to recite "an immune disorder", thereby providing explicit antecedent basis for the recitation of "said immune disorder" in claim 57. Accordingly, claim 57 is submitted to be compliant with 35 USC § 112, second paragraph, and withdrawal of Examiner's rejection is respectfully requested.

Claim Rejections Under 35 USC §102

In the Office Action claims 47 and 55 are rejected under 35 USC § 102(b) as being anticipated by Qu et al.

Applicants respectfully disagree with this rejection.

Qu et al teach an antisense compound targeted to a gene encoding an IL-2 protein (see Table 1). The IL-2 antisense was electroporated into mouse T cell lymphoma cells (TIB 155) and was shown to specifically inhibit IL-2 mRNA expression (for example, see Figure 3). Qu et al conclude that selective inhibition of IL-2 mRNA *in vivo* inhibits T-cell function and extends allograft survival. However, no where does Qu et al teach or suggest targeting of "a surface marker,

a chemokine, a cytokine, an enzyme or a transcriptional factor produced within an antigen presenting cell" as recited in the presently claimed invention.

The Examiner will kindly note that IL-2 production is known to occur in T cells, and more specifically Th1 cells, and to Applicants' knowledge has never been shown to be produced to any significant degree, in naturally occurring antigen presenting cell population. Indeed the knowledge available in the relevant art would direct the skilled person to presume that the IL-2 antisense oligo disclosed by Qu et al would be working through limiting IL-2 production in T cells, and not through any antigen presenting cell pathway. The skilled person would not consider antigen presenting cells, as IL-2 has never been shown to be produced in such cells.

Thus the disclosure of Qu et al is clearly directed to targeting of IL-2 in T cells, and not antigen presenting cells. In contrast, the presently claimed invention specifies targeting of molecules produced within an antigen presenting cell.

For at least these reasons claims 47 and 55 are submitted to be novel over the Qu et al reference and are submitted to be compliant with 35 USC § 102(b), and withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 USC § 103

In the Office Action claims 47 – 48, 53, 55 – 57 and 61 are rejected under 35 USC § 103(a) as being unpatentable over the combination of the Qu et al reference discussed above as well as Hammond et al and Tuschl et al.

As discussed above Qu et al is limited to targeting a IL-2 in T cell populations, and would be recognized as such by the skilled person. More specifically, the skilled person would recognize that the teachings of Qu et al could not be applied to antigen presenting cell populations as antigen presenting cells have never been shown to produce IL-2.

Hammond et al and Tuschl et al are focused on siRNA technology and provide no teachings of suppressing T cell activity by targeting a molecule produced within an antigen presenting cell. Therefore, Hammond et al and Tuschl

et al provide no teaching or suggestion to remedy the deficiency of Qu et al. Accordingly, the presently claimed invention is submitted to be patentable over Qu et al, Hammond et al and Tuschl et al, either alone or in combination.

For at least these reasons, the presently claimed invention is submitted to be compliant with 35 USC § 103(a) and withdrawal of this rejection is respectfully requested.

Maintaining Claim Rejections Under 35 USC § 101 and 35 USC § 112

In the Office Action, rejection of claims 22, 24 and 27 under 35 USC § 101 and 35 USC § 112, second paragraph, has been maintained on the basis that these claims fail to recite any active, positive steps limiting how the claimed use is practiced. Applicant respectfully disagrees that recitation of an active positive step is required. However, for the purpose of advancing prosecution claim 22 has been amended to recite an active "preparing" step. Accordingly, claims 22, 24 and 27 are submitted to be compliant with 35 USC § 101 and 35 USC § 112, second paragraph, and withdrawal of this rejection is respectfully requested.

Applicant respectfully requests reconsideration of the application. The Examiner may contact the undersigned should any clarification be required.

Respectfully submitted,
SIM & MCBURNEY

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